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10/574,740	01/22/2007	Patrick Schweizer	MA1WAM7.005APC	1910

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EXAMINER	
IBRAHIM, MEDINA AHMED	

ART UNIT	PAPER NUMBER
1638	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/574,740	SCHWEIZER ET AL.	
	Examiner	Art Unit	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 21-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-18 and 21-34* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 08/04/08 in reply to the Office action of 05/02/08 has been entered. Claim 1 is amended. Claims 33-34 are added. Therefore, claims 1-34 are pending and are examined.

All previous objections and rejections not set forth below have been withdrawn in view of Applicant's amendment to the claims.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 3-18, and 21-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a recombinant promoter comprising promoter sequence of SEQ ID NO: 1 and the intron sequence of SEQ ID NO: 2, a chimeric gene comprising said recombinant promoter operably linked to a coding sequence of interest, a method of transforming a plant with said chimeric gene, and a transgenic plant and progeny thereof comprising said recombinant promoter or chimeric gene, does not reasonably provide enablement for a promoter region having at least 90% sequence identity to SEQ ID NO: 1 or 2 , or a functional part of SEQ ID NO: 3 or a sequence that hybridizes thereto under stringent conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record as set forth in the last Office action of 05/02/08. Applicant's arguments filed 05/02/08 have been fully considered but are not deemed persuasive.

Applicant asserts that the claimed invention is fully enabled by the instant specification and that a skilled artisan can practice the full scope of the claimed invention without undue experimentation. Applicant cites in re Wands factors 858 F.2d 731,736-7, 8 U.S.P.Q.2d 1400, (Fed. Cir. 1988) to support this position. The breadth of the claims: Applicant asserts that claim 1 has been amended to recite the first and second sequences of the promoters are SEQ ID NO: 1 and SEQ ID NO: 2 and the promoter regions having at least 90% sequence identity to SEQ ID NO: 1 and 2. Applicant also asserts that new claim 34 recites the first and/or second sequence of the promoter region hybridizes under stringent conditions to the sequences of SEQ ID NO. 1 and/or SEQ ID No. 2. Applicant argues that since claims 1 and 34 both recite functional and structural limitations, the enablement requirement regarding the breadth of the claims is fulfilled.

These are not found persuasive because the breadth of the claims is not commensurate in scope with the enabling disclosure taking into account in re Wands factors. The scope of the claims encompasses sequences with multiple of nucleotide modifications including multiple of nucleotide substitutions and deletions in SEQ ID NO: 1, 2, and 3, promoter regions comprising a "functional part" of SEQ ID NO: 3 and promoter regions that hybridize under stringent conditions to SEQ ID NO: 3, wherein the

modified sequences retain the desired promoter and regulatory activities. The specification, however, does not provide guidance for internal deletion/substitution analysis in SEQ ID NO: 1, 2 or 3 to show which regions/parts of the sequences are required for epidermis-specific promoter/or intron regulatory function. The specification does not show which functional part/fragment in the 2553 nucleotide long sequence of SEQ ID NO: 3 would provide epidermis-specific expression of a desired gene. The specification provides guidance only for the promoter sequence of SEQ ID NO: 1 operably linked with the intron sequence of SEQ ID NO: 2 to form SEQ ID NO: 3 that control epidermis specific expression of a desired structural DNA.

Applicant asserts that since the level of skill in the art at the time this application was filed is high and the instant specification provides working examples encompassing the claimed invention, a skilled artisan would know how to make promoter regions with at least 90% or 95% sequence identity to the sequence of SEQ ID NO: 1- 2 or promoter regions that hybridize under stringent conditions to the sequence of SEQ ID NO: 1 or 3. Applicant points to pages 7-8 and 5-6 of the specification for guidance of how to make variants of sequences having at least 90% or 95% and hybridizing sequences and "functional parts". Applicant asserts that the Patent Office has determined, in Example 9 of the *INTERIM WRITTEN DESCRIPTION GUIDELINES TRAINING MATERIALS* that the language high stringent conditions does not encompass substantial variation among the species encompassed within the genus. Applicant, therefore, requests that the rejection be withdrawn.

These are not found persuasive because Applicant's arguments are not commensurate in scope with the claims. The specification provides general guidance, not specific, for how to make promoter sequences comprising with at least 90% or 95% identity to the sequences of SEQ ID NO: 1 and SEQ ID NO: 2 or 3; sequences that hybridize to SEQ ID NO: 1-3 under high stringency conditions, wherein the promoter sequences control epidermis specific expression of a desired gene in a transgenic plant. At pages 7-8, the specification provides a broad definition of "stringent hybridization conditions" and examples of conditions under which stringent hybridization may occur. The specification also discloses general guidance to determine promoter variants with 90% or 95% identity to SEQ ID NO: 1, 2, or 3. The specification does not provide specific guidance regarding which regions in the disclosed sequences can be modified to obtain sequences having both the structural and functional properties as recited in the claims.

At pages 5-6 of the specification, a "functional part" is broadly defined as "sequences, which the transcription complex, despite a slightly deviating nucleic acid sequence, can still bind to and cause epidermis-specific expression. Functional parts of a promoter sequence also comprise such promoter variants, whose promoter activity is lessened or enhanced in comparison with the wild-type. In particular, a functional part is, of course, also understood to denote natural or artificial variants of the sequence of the promoter region given in SEQ ID NO: 3. Mutations comprise substitutions, additions, deletions, exchanges, and/or insertions of one or more nucleotide residue/s." The specification, however, provides no guidance as how to

modify these regions to retain the epidermis-specific promoter activity. In addition, the modification to the sequences is not limited to the promoter regions in SEQ ID NO: 1 or 3, but also to the intron sequence of SEQ ID NO: 2 (see claims 1, 3, and 33-34). The specification is silent with respect to how and where to modify the intron sequence of SEQ ID NO: 2 to retain the intron regulatory activity.

Regarding Example 9 of the *INTERIM WRITTEN DESCRIPTION GUIDELINES TRAINING MATERIALS,* it is noted that the instant rejection is based on lack of scope of enablement rather than lack of written description.

Furthermore, the working examples disclosed in the specification is limited to the use of the unmodified sequences of SEQ ID NO: 1 and 2 or SEQ ID NO: 3, therefore, the ability of SEQ ID NO: 1 and 2 or 3 to provide epidermis specific expression of a desired gene cannot be extrapolated to all variants of SEQ ID NO: 1-3 as recited in the claims, absent specific guidance as to how and where to modify SEQ ID NO: 1-3 so as the epidermis specific expression is retained.

In *Genentech Inc. v. Novo Nordisk* A/S (42 USPQ2d 1001 at p. 1005) The CAFC stated "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not workable…While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention…[W]hen there is no disclosure of any specific starting material or of any of the conditions under which a

process can be carried out, undue experimentation is required.... It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement". Id. In this case, as in *Genentech*, the specification does not provide the "reasonable detail .....to enable members of the public to understand and carry out the invention" as broadly claimed.

Given that the broad scope of the claims; the limited guidance and working examples in the specification; the lack of guidance in the prior art regarding epidermis-specific promoter modifications; the unpredictability inherent in modifying multiple nucleotides in regulatory sequences like promoters and introns as known to one of ordinary skill in the art, it is concluded that undue experimentation would be required to practice the full scope of the claims, and therefore the invention is not enabled.

Written Description

Claims 1, 3-18, and 21-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Office action of 05/02/08. Applicant's arguments filed 08/04/08 have been fully considered but are not deemed persuasive.

Applicant argues that instant claims have been amended to recite promoters wherein the first sequence is SEQ ID No. 1 and the second sequence is SEQ ID No. 2 or wherein the first and/or second sequence of the promoter region have at least 90%

identity to the sequences of SEQ ID No. 1 and/or SEQ ID NO: 2; and promoter regions that hybridize under stringent conditions to the sequences of SEQ ID NO: 1, 2 or 3 and wherein the promoter regions provide specificity for plant epidermis. Applicant also argues that PTO has determined in Example 9 of the *INTERIM WRITTEN DESCRIPTION GUIDELINES TRAINING MATERIALS* that the language "stringent hybridization conditions" does not encompass substantial variation among the species of the genus of sequences claimed and that high stringency would yield structurally similar DNA sequences. Applicant concludes that since the claims recite both structural and functional limitations, the level of skill in the art is high; and the specification provides various regions and/or motifs required for promoter activity, the claimed invention is adequately described and that one of skilled in the art would recognize that Applicant was in possession of the invention as broadly claimed. Applicant requests that the rejection be withdrawn.

These are not found persuasive because the specification neither describes a representative species of promoter sequences of the genus of epidermis-specific promoter sequences encompassed by the instant claims, nor that it provides significant specific structural elements that are common to all epidermis-specific promoters.

Example 6 of the *WRITTEN DESCRIPTION TRAINING MATERIALS* provides Claim 3, directed to a DNA that encodes a protein that binds to a specific receptor and stimulates tyrosine kinase activity, wherein the DNA hybridizes under highly stringent conditions to the complement of SEQ ID NO: 1. The example states "because hybridization under highly stringent conditions requires high degree of structural complementarity, nucleic

acids that hybridize to the complement of SEQ ID NO: 1 must share many nucleotides in common with SEQ ID NO: 1.....However, without a recognized correlation between structure and function, those of ordinary skill in the art would not consider the Applicant to have been in possession of the claimed genus of nucleic acids based on the single species disclosed. Therefore, it concludes that claim 3 of the Example 6 fails to satisfy the Written Description Requirement. Therefore, a mere recitation of structural and functional properties in the claims would not obviate the rejection, absent specific guidance.

See, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. *See* also *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997) where it states "A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to all members of the genus, which features constitute a substantial portion of the genus. Therefore, for all the reasons discussed above and in the last Office action, the claimed invention is not adequately described. Therefore, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that one skilled in the art would recognize that Applicants are in possession of the invention as broadly claimed.

Remarks

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is

(571)272-0797. The examiner can normally be reached on M-TH 8:00 am to 5:30 PM, and every other Friday from 8:00 AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MAI
11/18/2008

/Medina A Ibrahim/
Primary Examiner, Art Unit 1638